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January 12, 2004

Via Hand Delivery

Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

***Re: Citizen Petition dated October 20, 2003 regarding FDA's gelatin guidance:
Docket No. 1997D-0411/CP1***

Dear Dr. Brackett:

We are writing on behalf of the Gelatin Manufacturers of Europe (GME) and the Gelatin Manufacturers Institute of America (GMIA). These trade associations represent producers of almost all of the gelatin made in Europe and North America.

On October 20, 2003, GME and GMIA submitted to FDA a Citizen Petition requesting that the agency modify a guidance document entitled *Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use* (Docket No. 97D-0411, September 1997) (the "gelatin guidance"). We understand that our petition has been assigned to CFSAN for action. A copy of our petition is enclosed.

Since our petition was submitted, two important events have occurred relating to the BSE issue. First, as you know, on December 23, 2003, the U.S. Department of Agriculture (USDA) identified a case of BSE in a cow located in the United States. We understand that this cow likely originated from a farm in Canada and that investigation of this matter is still ongoing. Second, on November 4, 2003, USDA published a proposed rule that would create a category of "minimal-risk" regions that would potentially be subject to import rules different than those applied to other BSE countries (68 FR 62386); we understand that USDA will reconsider this proposed rule based on new information about the BSE case identified in the United States.

These recent developments underscore the importance of acting promptly on our petition. Since FDA's gelatin guidance was issued in 1997, extensive studies commissioned by the European Commission and GME, and supported by GMIA, have been conducted on the extent to

97D-0411

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which the processing of gelatin provides a strong assurance that gelatin is safe. Data from these studies were presented to FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) at its meeting on July 17, 2003. The TSEAC reviewed these data in detail and voted that the data "demonstrate a reduction in infectivity that is sufficient to protect human health."¹ (Transcript of Meeting at 150, 158.)²

Our petition requests that FDA's gelatin guidance be revised to reflect this TSEAC conclusion. These revisions will result in a guidance that is consistent with the available scientific evidence and that provides a stronger assurance of safety than does the current document. Therefore, it continues to be important that FDA's gelatin guidance be promptly revised so as to provide consistent guidance for the many firms that use gelatin in FDA-regulated products, including pharmaceuticals, food, medical devices, and cosmetics.

It is our understanding that CFSAN is currently preparing a revised draft gelatin guidance. GME and GMIA would like to request a meeting with FDA to discuss our proposed revisions to the guidance. However, if FDA plans to fully implement the points requested in our petition, then we would not consider it necessary to meet (though we would of course be happy to do so if this would be of assistance to you).

Therefore, we would ask that you inform us of:

- (1) Proposed dates for a meeting to discuss our petition (or whether such a meeting will be unnecessary because FDA plans to fully implement the points requested in our petition); and
- (2) Any questions that FDA may have as it considers our petition, so that we may provide any further assistance that you may need.

¹ The vote was 7 in favor, 1 abstain, and 1 against.

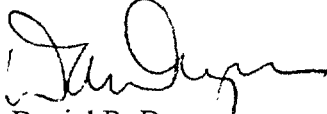
² See also, <http://www.fda.gov/ohrms/dockets/ac/03/minutes/3969M.htm>.

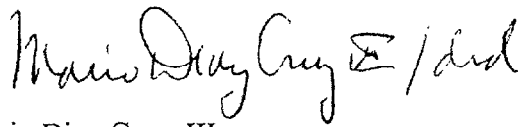
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Thank you for your kind assistance with this matter. Please contact Dan Dwyer with your response to this request.

Sincerely,


Daniel R. Dwyer
*Counsel to the Gelatin
Manufacturers of
Europe*


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Enclosure

cc (with enclosure):

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